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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,761	02/21/2006	Takamasa Watanabe	0020-5502PUS1	6669

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
02/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/568,761	WATANABE ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 February 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *5* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *19,20 and 31-35*.
   Claim(s) withdrawn from consideration: *None*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Maher M. Haddad/
Primary Examiner, Art Unit 1644

Continuation of 11. does NOT place the application in condition for allowance because:

A. Claims 19-20, 32 and 35 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S Pat. No. 6,423,501 for the reasons of record.

Applicant's arguments, filed 02/10/2010, have been fully considered, but have not been found convincing.

Applicants point out in conjunctions with case law that anticipation requires, in a single prior art reference, disclosure of each and evey element of the claimed invention, arranged as the claim. Applicant submtis that a reference must disclose within the four corners of the document not only all of the elements claimed but also all of the elements arranged or combined in the same way as recited in the claim. Applicant submtis that the Examiner relies upon a variety of different embodiments of Fleming et al., not directely related to each other, in an attempt to piece together all the recited claim elements; for example, the Examiner cites to col., 12, lines 34-45, to allege that fleming et al. discloses the treatment of inflammatory bowel disease, and col., 9, line 65 to col., 10, line 3, as allegedly disclosing anti-CD81 antibodies. However, the cited sections recite a plethora of alternative and distinct embodiments, and at no point does fleming et al disclose Applicants' claimed combination, arranged as described in the claims, in a single source so as to direct those skilled in the art to the claimed invention without any need for picking and choosing amongst these alteranative and distinct embodiments. To the contrary, th erejection is premised on picking and chosing between the distinict and alterantive embodiments recited in cloumns 9, 10 and 13 of fleming et al. Applicant contends that this is not the law. Piecing together Applicants' claimed invention by picking and choosing between alteranative and distinct embodiments, in the absence of any direct relation ship between alteranative and distinct embodiments, in the absence of any direct relationship between the selected embodiment -as is the case here, does not represent disclosure of the claimed invention "as arranged in the claim." and thus does not constitute anticipation. Specifically, Applicants submits that the Examiner's poition runs counter to the court's holding in Net MoneyIn, Inc., V. Verisign, Inc., 545 F.3d 1359 (Fed. Cir. 2008), wherein the Federal Circuit clarified that the test for anticipation is that a reference must not only disclose all elements of the claim within the four corners of the document, but those selected elements must be "arranged or combined in the same way as the claim," so as to prevent picking and choosing of unconnected elements to piece together a claimed invention. The court, citing In re Arkley, 455 F.2d 586 (C.C.P.A 1972), noted that "the prior art reference must clearly and unequivocally disclose the claimed invention or direct those skilled in the art to the invention without any need for picking, choosing, and combinding various disclosures not directely related to each other by the teachings of the cited reference." However, the instant rejections is prediated on exactly such picking and choosing; one of skill in the art would have to pick and choose between the plethora of alteranative and distinct embodiments recited in col., 9, 10 and 13 of Fleming et al., to arrive at Applicants' claimed invention, when no direct relationship between the selected elements has been disclosed. Consistent with the court's holding in In re Arkley, such picking and choosing is simply not permissible to sustain a finding of anticipation. Similarly, dure to the vast number of possible alternative embodiments disclosed of Fleming et al., as would be required to maintain inherently flow from those portions of Fleming et al, as would be required to maintain inherency on this basis. Applicant submits that it is well-settled law that the concept of inherent disclousre does not negate the requirement that the selected elements be disclosed in the same way as arranged in the claim without any need for picking and choosing.

However, in contrast to Net MoneyIN, Inc. v. VeriSign, Inc., wherein the claims are directed to processing credit card using multiple step transactions, the instant claimed method is a single method step that requires only the administeration of anti-CD-81 antibodies to a patient who is in need for imporing or treating of inflammatory bowel disease. It is not clear to the Examiner what Applicants ment by "all of the elements arranged or combined in the same way as recited in the claim," since there is only one element (anti-CD81 antibody) to be administered to IBD patient. The `501 patent teaches the use of an agent which induces CD81-mediated signal transduction to treat inflammatory condition such as IBD, wherein the agent is anti-CD81 antibodies. There is no picking and choosing of unconnected elements to piece togther Applicants' invention. It is the Examiner's position that the `501 patent discloses all of the limitations recited in claim 19 arranged or combined in the same way as in the claim. Applicants have not identified any manipulative difference between Fliming's method and the claimed method.

With respect to the statement made by the Examiner that "a patent is an enabling reference for all that it teaches", Applicant submits that this position is unsupported by law, an dindeed, vitiates the very requirement that an anticipatroy reference be enabling' under this standard, a reference would necessarily eable an invention so long as the claim elements were disclosed, irrespective of whether undue experimentation would be required. Applicant submits that this is not the law.

However, a patent shall be presumed valid (35 U.S.C. 282) until declared invalid in a court of competent jurisdiction, and that presumption includes the presumption of operability (Metropolitan Eng. Co. v. Coe, 78 F.2d 199, 25 USPQ 216 (D.C.Cir. 1935). The challenger of a patent's validity bears the burden of proving invalidity by clear and convincing evidence.

Applicant submits that it cannot be argued that Fleming qualifies as enabling prior art simply because it does not need not enable one of skill in the art to "use" the claimed invention (but rather only needs to eanble one of skill in the art to "make" the invention). Applicants submit that In re Gleaver, the "make" requirement becomes a "use" requirement when method-of-use claims are at issue.

In contrast to In re Gleave, the `501 patent does not only teach the anti-CD81 antibodies, but also teaches a method of using anti-CD81 antibodies to treat IBD. Accordingly, the `501 patent is enabled for how to make and use the anti-CD81-antibodies in treat IBD.

B. Claims 19-20, 32 and 35 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/25647 (IDS ref. No. BJ) for the reasons of record.

Applicant's arguments, filed 02/10/2010, have been fully considered, but have not been found convincing.

Applicants note that WO 98/25647 is the publication ofPCT/US97/22743, a continuation of U.S. Application No. 08/954,279, which issued as U.S. Patent No. 6,423,501 (i.e., Fleming et al., discussed above). Thus, Claims 19, 20, 32 and 35 are not anticipated by WO 98/25647 for the exact same reasons as discussed above in response to the rejection of Claims 19, 20, 32 and 35 over Fleming et al.

The Examiner's position is same as above.

C. Claims 19-20, 31-32 and 35 stand rejected under 35 U.S.C. 102(b) as being anticipated by Curd et al (WO 00/67796) for the reasons of record.

Applicant's arguments, filed 02/10/2010, have been fully considered, but have not been found convincing.

Applicants submit that the Examiner relies upon a variety of different and alternative embodiments of Curde, not directly related to each other, in an attempt to piece together all the recited claim elements. For example, the Examiner cites to claims 1-3 and 6-7 in an attempt to disclose the claimed invention. However, claim 2 encompasses a myriad of alternative and distinct B-cell surface antigens that may be antagonized, and Claim 6 recites a plethora of alternative and distinct diseases that may be treated by antagonism of a B-cell surface antigen. Claims 2 and 6 each recite a plethora of alterantive and distinct embodiments, and at no point does Curd discloses Applicants' claimed combination, arranged as described in the claims, in a single source so as to direct those skilled in the art to the claimed invention without any need for picking and choosing amongst these alternative and distinct embodiments. To the contrary, the rejection is premised on picking and choosing between the distinct and alternative embodiments recited in Claims 1,2, 3, 6 and 7. Piecing together Applicants' claimed invention by picking and choosing between alternative and distinct embodiments, in the absence of any direct relationship between the selected embodiments - as is the case here, does not represent disclosure of the claimed invention "as arranged in the claim," and thus does not constitute anticipation. See Net MoneyIN, Inc. v. Verisign, Inc., 545 F.3d 1359 (Fed. Cir. 2008); and In reArkley, 455 F.2d 586 (C.C.P.A. 1972). However, the instant rejection is predicated on exactly such picking and choosing; one of skill in the art would have to pick and choose from the plethora of possible alternative, and distinct, embodiments recited in Claims 1, 2, 3, 6 and 7 of Curd et al. to arrive at Applicants' claimed invention, when no direct relationship between the selected elements has been disclosed. Curd et al. thus fails to teach the invention as claimed in Claims 19, 20, 31, 32 and 35.

However, it remains the Examiner's position that Curd et al claims Applicant's invention arranged and sescribed in the claims (see published claims 1-3, and 6-7). Claims recite a common feature of B cell surface marker such as CD81 and different species of autoimmune disease treatable with the anti-CD81 antibody such as IBD indicate that these elements in the claims are essential material.

D. Claims 31 and 33-34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Pat. No. 6,423,501 or WO 98/25647 or WO 00/67796 in view of and Owens et al (1994) for the reasons of record.

Applicants submit that neither Fleming et al., WO 98/25647 nor WO 00/67796 disclose, expressly or inherently, a method of improving or treating inflammatory bowel disease comprising administering an anti-CD81 antibody to a patient in need thereof, and there exists nothing in these references that would incite ~ expectation of success in performing such a method. Further, because Owens et al. fails to rectify this deficiency, and merely discloses the use of antibody molecule variants, even assuming arguendo that one of ordinary skill in the art were to combine Fleming et al., WO 98/25647 or WO 00/67796 with Owens et al., they would not arrive at the presently claimed invention. Applicants respectfully submit that Claims 31, 33 and 34 are not rendered obvious for at least this reason.

It remains the Examiner's position the combined reference teachings arrived to the claimed invention.